

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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|--|--|--|------------------|
| Applicant's or agent's file reference C1-A0509P | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2006/311625 | International filing date (<i>day/month/year</i>) 09 June 2006 (09.06.2006) | Priority date (<i>day/month/year</i>) 10 June 2005 (10.06.2005) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA | | | |

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

- This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 11 December 2007 (11.12.2007) |
| | Authorized officer Yoshiko Kuwahara e-mail: pct@wipo.int |

PATENT COOPERATION TREATY

TRANSLATION

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

C1-A0509P

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2006/311625

International filing date (day/month/year)

09.06.2006

Priority date (day/month/year)

10.06.2005

International Patent Classification (IPC) or both national classification and IPC

Applicant

CHUGAI SEIYAKU KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/Z20 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/Z20.

3. For further details, see notes to Form PCT/ISA/Z20.

| | | |
|--|------------------------------------|--------------------|
| Name and mailing address of the ISA/JP | Date of completion of this opinion | Authorized officer |
| Facsimile No. | | Telephone No. |

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

| WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY | | International application No. PCT/JP2006/311625 | | | |
|---|--|--|--|--|--|
| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | |
| <p>1. Statement</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;"> <p>Novelty (N)</p> <p>Inventive step (IS)</p> <p>Industrial applicability (IA)</p> </td> <td style="width: 40%; vertical-align: top;"> <p>Claims <u>3-4, 11-12, 18-21</u></p> <p>Claims <u>1-2, 5-10, 13-17</u></p> <p>Claims _____</p> <p>Claims <u>1-21</u></p> <p>Claims <u>1-21</u></p> </td> <td style="width: 30%; vertical-align: top;"> <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> </td> </tr> </table> | | | <p>Novelty (N)</p> <p>Inventive step (IS)</p> <p>Industrial applicability (IA)</p> | <p>Claims <u>3-4, 11-12, 18-21</u></p> <p>Claims <u>1-2, 5-10, 13-17</u></p> <p>Claims _____</p> <p>Claims <u>1-21</u></p> <p>Claims <u>1-21</u></p> | <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> |
| <p>Novelty (N)</p> <p>Inventive step (IS)</p> <p>Industrial applicability (IA)</p> | <p>Claims <u>3-4, 11-12, 18-21</u></p> <p>Claims <u>1-2, 5-10, 13-17</u></p> <p>Claims _____</p> <p>Claims <u>1-21</u></p> <p>Claims <u>1-21</u></p> | <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> <p>YES</p> <p>NO</p> | | | |
| <p>2. Citations and explanations:</p> <p>The following documents are presented in the ISR:</p> <p>Document 1: JP, 3-41033, A (KYOWA HAKKO KOGYO CO., LTD.) Document 2: JP, 2004-292455, A (Chugai Pharmaceutical Co., Ltd.) Document 3: WO, 2004-037293, A (Dainippon Sumitomo Pharma Co., Ltd.)</p> <p>Regarding Claims 1-2, 5-10, and 13-14:</p> <p>Document 1 discloses the technical feature of adding a sugar in order to stabilize motilin or the like that is, for example, a protein. Document 1 illustrates meglumine as an example of the added sugar. Document 1 also discloses the technical feature of obtaining a lyophilized preparation by performing a lyophilizing step, after performing the step of adding the stabilizer such as meglumine to motilin or the like that is, for example, a protein.</p> <p>Consequently, the subject matters of claims 1-2, 5-10, and 13-14 in the present international application do not appear to be novel or to involve an inventive step over document 1.</p> <p>Regarding claims 3-4, 11-12, and 18-21:</p> <p>The subject matters of claims 3-4, 11-12, and 18-21 in the present international application are different from the disclosure in document 1 in that the protein is an antibody molecule.</p> <p>However, document 2 discloses that, when a protein is stored in a solution having a high concentration, a problem may arise where a degrading phenomenon such as generation of an insoluble aggregate occurs, and that it is necessary to prevent the problem from occurring. In particular, in view of the problem where an aggregate is easily generated when an antibody preparation is stored in a solution state, and thus an insoluble aggregate may be generated, document 2 also discloses the technical feature of adding a stabilizer made of a sugar to the antibody.</p> <p>Consequently, it would have been obvious to a person skilled in the art to use an antibody instead of motilin or the like as the protein in the disclosure of document 1 so as to test and confirm the stabilizing effect of meglumine.</p> <p>As a result, the subject matters of claims 3-4, 11-12, and 18-21 in the present international application appear to be novel but do not appear to involve an inventive step over documents 1 and 2.</p> <p>Regarding claims 15-17:</p> <p>Document 3 discloses a pharmaceutical composition into which meglumine has been added as a stabilizer. Document 3 also discloses that the preparation may be in the form of a lyophilized preparation.</p> <p>Accordingly, the subject matters of claims 15-17 in the present international application do not appear to be novel or to involve an inventive step over document 3.</p> | | | | | |